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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/765,244	01/26/2004	Pierre H. Turpin	CLON-107	1759
24353	7590	02/10/2006	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			KETTER, JAMES S	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/765,244	Applicant(s) TURPIN ET AL.	
	Examiner James S. Ketter	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 19, 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20, 21 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/05</u> | 6) <input type="checkbox"/> Other: _____ |

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Applicant's election with traverse of Group I, claims 18-21, and the species ZsProSEnsor-1, in the reply filed on 4 January 2006 is acknowledged. The traversal is on the ground(s) that there would be no undue burden to examine all claims together. This is not found persuasive for of the reasons of record set forth in the restriction requirement. Applicant has not provided a specific reason why the search would not be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 19, 22 and 23 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4 January 2006. Applicants noted that claim 19 does not read upon the elected species, and claims 22 and 23 are drawn to the non-elected invention, i.e., Group II.

Claims 9, 11, 12, 17, 20, 21, 25, 27-29 are objected to because of the following informalities:

In claim 9, "florescent" should be spelled "fluorescent".

In claim 11, line 1, "report" should be "reporter".

In claim 11, line 2, "RCFPs" should be spelled out, or the acronym should be associated with the term in claim 10.

In claim 12, "an" should be "a".

In claim 17, line 2, the comma after "group" should be a colon.

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In claim 20, line 2, the comma after “following” should be a colon.

In claim 21, line 3, “side” should be “sides”.

In claim 25, line 1, “are” should be “is”.

In claim 27, line 1, “ZLLH” should be spelled out.

In claim 28, line 1, “ALLN” should be spelled out.

In claim 29, line 2, the comma after “following” should be a colon.

Appropriate correction is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

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The elected species, i.e., ZsProSensor-1, shown in Figures 1A and 1B, appears to be free of the cited prior art. However, prior art relevant to the linking claims and generic embodiments in the elected claims is applied in the rejections below.

Claims 1-18, 20, 21 and 24-29 are rejected under 35 U.S.C. 102(e) as being anticipated by Lukyanov et al. (A, newly cited).

Claim 1 is drawn to a proteasome sensor comprising an indicator molecule a protein degradation tag. Claim 2 specifies that the construct is a nucleic acid, more narrowly claimed as DNA in claim 3. Claim 4 recites that the construct is in a vector, more narrowly specified as a plasmid or viral vector in claim 5. Claim 6 specifies that the construct is RNA, and claim 7 specifies that it is a protein. Claim 8 specifies that the reporter is observable in a cell. Claim 9 specifies that the reporter is a fluorescent protein, more narrowly recited as a reef coral fluorescent protein in claim 10. Claim 11 still more narrowly specifies that the reporter is selected from the recited listing, which includes ZsGreen, with claim 12 specifying that it is from a medusa organism. Claim 13 specifies GFP or a mutant. Claims 14-16 are unclear (see rejection under 35 USC §112, second paragraph, below), with limitations regarding process of using steps recited. Claim 17 recites that the protein degradation tag is from a pest system, ubiquitin system or another system, with claim 18 limited to the pest system. Claim 20 recites that the tag is rich in proline, glutamic acid, serine and/or threonine. Claim 21 appears to recite that the tag is at least 1 amino acid longer than the minimally effective sequence. Claims 24-29 also recite process of using limitations despite the claims being drawn to products, and as such, are also unclear.

At page 16, paragraph [0174], Lukyanov et al. teaches a fusion of a fluorescent protein with the PEST sequence from mouse ornithine decarboxylase gene (MODC). At, e.g., page 18, paragraph [0207], it is specifically taught that the MODC gene sequence can be used as a transcriptional reporter in a plasmid. At pages 4 and 5, paragraphs [0062] and [0063] teach that ZsGreen is one of the contemplated fluorescent proteins for use in the invention of Lukyanov et al. Thus, Lukyanov et al. teaches a DNA construct which is in a plasmid, which construct comprises MODC fused to ZsGreen reporter gene, ZsGreen fluorescing visible green light. RNA and protein are inherently expressed from the gene construct. With respect to claim 20, the PEST sequence is by inherently rich in one or more of the recited amino acids. With respect to claim 21, it is not apparent that the sequence used and taught by Lukyanov et al. is only the minimal sequence, and thus encompasses the extended sequence as claimed.

Claims 1-10, 12-18, 20, 21 and 24-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (U, newly cited).

The relevant claims are described above.

Li et al. teaches, e.g., as summarized in the abstract, a fusion of MODC to a green fluorescent protein. At page 34971, left-hand column, in the first paragraph of "Experimental Procedures", a DNA vector encoding this fusion protein is taught, with its expression (as RNA and protein) taught in the subsequent three paragraphs and at Figure 1. With respect to claim 20, the PEST sequence is by inherently rich in one or more of the recited amino acids. With respect to claim 21, it is not apparent that the sequence used and taught by Li et al. is only the minimal sequence, and thus encompasses the extended sequence as claimed.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-18, 20, 21 and 24-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, and therefore claims 2-18, 20, 21 and 24-29 which depend therefrom, refers to the proteasome sensor as “sensitive”. However, this is a relative term not defined by the specification, and thus renders unclear the metes and bounds of the claims.

Claims 2-6 are drawn to the “construct” of claim 1. However, claim 1 is drawn to a proteasome sensor, and as such, the metes and bounds of claims 2-6 are unclear.

Claim 11, recites “from the group comprising”. However, this is not proper Markush-type language, as the openness of the language renders the definition of the group, and thus the entire claim, indefinite.

Regarding claim 13, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 14-16 employ disjointed grammar, such that the meaning of the claims is unclear. The phrase “protein a delay of” cannot be understood clearly.

Claim 17, and therefore claim 18 which depends therefrom, recites “pest system, ubiquitin system, or other systems”. However, this limitation exhausts the field of protein degradation tags because of the phrase “or other systems”. As such, it is not clear how this claim differs from claim 1.

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Claim 20 recites “is rich in”. However, this is a relative term not defined by the specification, and thus renders unclear the metes and bounds of the claims.

Claim 21 recites “minimally effective tag”. However, it is not clear what constitutes “minimally effective”. As such, the metes and bounds of the claim are not defined.

Claim 21 appears to have disjointed grammar. There is a period at the end of line 2, followed in line three by the word “include”. However, the grammar of the claim is thus rendered unclear, as it is not apparent what the subject of “include” is meant to be.

Claim 21 recites “with...being the preferred range...” and “...being the most preferred range.” However, these phrases render the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Stated otherwise, it is not clear if the claims are limited to the preferred or more preferred scope.

Claim 24, and therefore claims 25-28 which depend therefrom, recites “high sensitivity”. However, this term is not defined, and is of relative degree, thus rendering the metes and bounds of the claim unclear.

Claims 24-29 are drawn to a product, i.e., the construct, but appear to include process of using limitations. These steps are not merely intended uses. As such, the meaning of each claim is unclear, as is the statutory class of each claim.

Claims 25-28 recites “preferably” and “most preferably”. However, these phrases render the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d). Stated otherwise, it is not clear if the claims are limited to the preferred or more preferred scope.

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Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (571) 272-0770. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (571) 272-0781.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Jsk
February 2, 2006



**JAMES KETTER
PRIMARY EXAMINER**